

**REMARKS**

Claims 14, 20, 21 and 32 have been amended, and claims 25 and 29 have been cancelled by this amendment. No new matter has been added.

Claims 1-13, 33-60 and 67-86 were previously withdrawn.

Claims 14, 16-18, 20-24, 26-28 and 30-32 are now pending in the application.

**Claim Objection**

Claim 20 was objected to under 37 CFR (c) as being improper form because it depends on a currently cancelled claim (i.e. claim 19).

Applicants have amended claim 20 to depend on claim 14 by this amendment to fully address this objection.

**Claims Rejection – 35 USC § 112**

Claims 14, 16-18, 21-28, and 30-32 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Of the rejected claims, claims 25 and 29 have been cancelled, claim 14 is independent, with the remaining claims dependent thereon.

Claim 14 has been amended to incorporate the limitations of claim 29 such that amended claim 14 now recites a thixotropic gel.

Claim 29 was not included in this §112 rejection, and thus this rejection is rendered moot.

### **Claims Rejections – 35 USC § 102 and § 103**

Claims 14, 16-18 and 21-32 are rejected under 35 U.S.C. 102(b) as being anticipated by or in the alternative under 35 U.S.C. 103(a) as obvious over US Patent No. 4,350,593 to Kessler ("Kessler").

Applicants respectfully traverse this rejection.

Of the claims rejected, claims 25 and 29 have been cancelled, claim 14 is independent, with the remaining claims dependent thereon.

Amended claim 14 now recites among other things:

*a thixotropic gel located in the container in contact with a portion of the inner wall, wherein the thixotropic gel comprises continuous first and second regions, the first region located at or adjacent to the lower end, and the second region extending upward from a portion of the first region, wherein the first region comprises an imaginary upper boundary at which the first region exhibits 360° circumferential contact with the inner wall, and wherein the first region comprises at least about 80 vol.% of the thixotropic gel.*

The MPEP section 2131 on Anticipation — Application of 35 U.S.C. 102(a), (b), and (e) [R-1] states: TO ANTICIPATE A CLAIM, THE REFERENCE MUST TEACH EVERY ELEMENT OF THE CLAIM

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053(Fed. Cir. 1987).

Applicants submit that Kessler fails to disclose at least the claimed feature of the first region comprising at least about 80 vol.% of the gel.

The Examiner states in the Final Office Action dated April 10, 2008:

"The thixotropic gel of Kessler is specifically cited in Applicant's instant specification as capable of being advantageously used in the invention, see par. [0033] of the instant specification. Thus, the Examiner asserts that since the claimed and prior art gels are identical or substantially identical in structure or composition a prima facie case of anticipation is established. Further, since the claimed and prior art gels are identical or substantially identical in composition, they must necessarily exhibit the same rheological properties under the same conditions (i.e., in a container). That is, the first region of the gel of Kessler inherently comprises a first region with at least about 80 vol. % of the gel (claim 14), distance between the first and second regions being between 8 to 21 mm (claims 17-18), and the second region exhibits less than 180 degree circumferential contact with the inner wall (claim 27), etc., since See MPEP 21 12.02."

Applicants respectfully point out that claim 14 is directed to a specific geometry (and not a composition or structure) for a thixotropic gel disposed in a container which overcomes potential gel movement issues.

Kessler is completely silent in regard to the vol% of gel within the first region.

Conversely, Applicants have discovered that the specific geometry or shape of a gel has a significant effect of the movement of the gel during centrifugation and on the separation performance of the gel barrier, thus a common gel having different geometries within two tubes will have different movement properties during a common centrifugation.

The specific geometry of a gel within a tube is controlled by numerous variables or conditions including for example; the angle of the tube during gel deposition, the temperature of the gel during dispensing, the mechanical history of the gel prior to dispensing, the cooling profile of the gel post dispensing.

Thus Kessler fails to inherently disclose at least the claimed feature of the first region comprising at least about 80 vol.% of the gel.

For these reasons, applicants submit that independent claim 14 and dependent claims 16-18 20-24, 26-28 and 30-32, are not anticipated by the Kessler reference.

Furthermore, the invention defined by amended claim 14, is neither taught nor rendered obvious by Kessler. Kessler has no suggestion of the first region of a gel comprising at least about 80 vol.% of the gel and is silent in regard to the amount of vol.% of the gel which should be present in the first region.

Therefore, Kessler fails to acknowledge or teach the importance that the vast majority of the gel be at or near the bottom of the tube in the first region.

The Examiner further states:

"However, even if Kessler does not inherently teach the first region comprising at least about 80 vol. % of the gel, it would have been obvious to one having ordinary skill in the art at the time of the claimed invention to use a gel possessing rheological properties such that at least about 80 vol. % of the gel remains at the bottom of the container (i.e., in the first region), since this would reduce the likelihood of the gel leaking out of the top of container during shipping and storage."

Applicants respectfully point out that one skilled in the art understands that the claimed thixotropic gel is designed to only move under a specific yield stress during centrifugation. Therefore the gel does not substantially move during shipping and storage. Thus one skilled in the art would not have considered the likelihood of the gel moving or leaking out of the top of

container during shipping and storage as motivation to for the first region comprising at least about 80 vol. % of the gel.

Kessler and US Patent No. 3,997,442 to Gigliello et al. (submitted in an IDS filed September 18, 2003) teach that at the time of invention the shape or geometry of the gel is designed to cause gel movement to occur at the earliest possible stages of centrifugation, (see Col. 4 lines 19- 38 of Kessler, shown below) in order to form a barrier as soon as possible during centrifugation:

In the preferred embodiment assembly of the invention, a barrier 22 having a relatively high yield stress value, i.e.; on the upper side of the above-specified range, may not flow immediately under normal centrifugal forces if the upper surface 23 is a plane perpendicular to the axis A of the tube 12. This is because the shear stress developed under the preferred normal centrifugal forces is less than the yield stress of the barrier material and is due to the symmetry of the configuration of the disposed barrier 22. Under such circumstances, increasing the centrifugal force is not desirable or practical since it may result in the rupture of cellular blood components with the consequent release of cellular fluids or may not be possible due to limitations of available centrifuging equipment. To overcome this situation, the preferred assembly of the invention comprises one as illustrated in the assembly 10 wherein barrier material 22 is disposed as shown in FIG. 2 with the surface 23 forming other than a plane perpendicular to the axis A of the tube 12.

In contrast, applicants claimed gel geometry in which the vast majority of the gel is in the bottom first region causes slower gel movement during centrifugation and therefore a longer time to form a barrier.

Thus Kessler teaches away from the claimed invention.

Applicants have discovered that gel geometries which do not have the vast majority of the gel be at or near the bottom of the tube in the first region (such as disclosed in Kessler and Gigliello) result in the gel overshooting the final equilibrium separating position before settling back to the final equilibrium separating position, poor barrier properties, sample entrapment in the barrier and premature barrier formation during centrifugation before separation of the sample has been completed.

This conclusion is demonstrated by an experimental comparison of gel bias angle between the claimed gel geometry and the gel geometry of Kessler and Gigliello performed by Inventor Dimitrios Manoussakis and submitted as a Rule 1.132 Declaration herewith.

For these reasons, applicants submit that independent claim 14 and dependent claims 16-18 20-24, 26-28 and 30-32, are not taught or suggested by the Kessler reference.

**Conclusion**

In view of the amendment and remarks herein, applicants submit the claims are patentably distinct over the prior art and allowable in form.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 02-1666.

If the Examiner has any questions or comments relating to the present application, he or she is respectfully invited to contact applicants' agent at the telephone number set forth below.

Respectfully submitted,

/Mark Lindsey/

Mark Lindsey  
Registration No. 52,515  
Agent for Applicant(s)  
201 847 6262

Dated: October 8, 2008.  
Becton, Dickinson and Company  
1 Becton Drive, MC110  
Franklin Lakes, New Jersey 07417-1880

Doc# 143692v1